

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

A.L., a minor, by and through her mother  
Alexandra Agodon,

Plaintiff,

v.

Gerber Products Company; Nestle S.A; Plum,  
PBC, d.b.a. Plum Organics; Campbell Soup  
Company; and Sprout Foods, Inc.,

Defendants.

CASE NO.: 24-cv-3141

**COMPLAINT FOR DAMAGES**

**DEMAND FOR JURY TRIAL**

*The Judicial Panel on Multidistrict Litigation has transferred certain personal injury product liability actions relating to baby food products to the United States District Court for the Northern District of California for coordinated pretrial proceedings. The coordinated proceeding is MDL 3101 In Re: Baby Food Products Liability Litigation (N.D. Ca. 24-md-3101-JSC) and Plaintiff is filing this case as a “tagalong action” that is intended to later be transferred to that MDL.*

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## **INTRODUCTION**

1. This case involves a couple of manufacturers/sellers—namely, Gerber Products Company, Nestle S.A., Plus Organics, Campbell, and Sprout Foods, Inc. (“Defendants”)—that *knowingly* sold baby food products (“Baby Foods”) which contain dangerous levels of toxic heavy metals—lead, arsenic, and mercury (collectively “Toxic Heavy Metals”), which are known to be severe neurotoxins—and how such toxic exposures substantially contributed to Plaintiff developing lifelong brain injury. Plaintiff is a child who lives with debilitating brain injury, namely in the form of the neurodevelopmental disorder autism spectrum disorder (“ASD”) and related *sequelae* because, as an infant, he consumed poisonous Baby Foods manufactured and/or sold by these Defendants. This case seeks to hold the Defendants accountable for their reprehensible conduct and ensure they are punished for permanently affecting Plaintiff’s ability to live a fulfilling life.

2. That Defendants’ Baby Foods are laced with staggering amounts of Toxic Heavy Metals recently made headlines following research and a Congressional investigation. In February 2021, the U.S. House of Representatives’ Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform released a report containing shocking details of Defendants’ tainted Baby Foods based on the submission of internal test results and company documents. Specifically, the Subcommittee found that Defendants sell Baby Foods containing levels of heavy metals ranging from tens to hundreds of parts per billion (“ppb”),<sup>1</sup> far eclipsing domestic and international regulatory standards. With a chilling note the Subcommittee concluded that “[m]anufacturers *knowingly* sell these products to unsuspecting parents, in spite of internal company standards and test results, and without any warning labeling whatsoever.”<sup>2</sup> (emphasis added).

3. The high levels of Toxic Heavy Metals found in Defendants’ Baby Foods are, in part,

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<sup>1</sup> Ppb (or ppbm) is used to measure the concentration of a contaminant in soils, sediments, and water. 1 ppb equals 1 µg (microgram) of substance per kg of solid (µg/kg). For the average baby weighing approximately 3kg, the quantities of Toxic Heavy Metals found in Defendants’ Baby Foods, as explained below, pose significant health risks.

<sup>2</sup> Staff Report, Subcommittee on Economic and Consumer Policy Committee on Oversight and Reform U.S. House of Representatives, *Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury* (Feb. 4, 2021) (“Subcommittee Report”) at 59, available at: <https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf>

a function of the ingredients used by Defendants to manufacture their Baby Foods, the setting of dangerously inflated internal limits which Defendants willingly flouted, disregard of regulatory standards, and corporate policies which failed to test finished products before market distribution, purchase by unknowing parents, and consumption by vulnerable infants.

4. Defendants' malicious recklessness and callous disregard for human life has wreaked havoc on the health of countless vulnerable children, all so that Defendants could maximize profits while deliberately misleading parents regarding the safety of their Baby Foods. Accordingly, this lawsuit will not only ensure that Plaintiff is duly compensated for his tragic injuries and Defendants punished, but that future generations are protected from the poisonous products that Defendants pander as "food".

## **PARTIES**

### **I. Plaintiff**

5. Plaintiff is a citizen of New York and no other state.

### **II. Defendants**

6. Defendant Gerber Products Company ("Gerber") is a citizen of Michigan and Virginia with its principal place of business located at 1812 N. Moore Street, Arlington, VA 22209. Gerber sells Baby Foods under the brand name Gerber. Gerber organizes its products into broad categories of "formula", "baby cereal", "baby food", "snacks", "meals & sides" "beverages" and "organic". At all relevant times, Gerber has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Baby Foods within this judicial district.

7. Defendant Nestle S.A. ("Nestle") is a citizen of Switzerland, with its principal place of business located at Avenue Nestle 55, 1800 Vevey, Switzerland. Nestle is a global food and beverage company with more than 2,000 brands, and sells Baby Foods under its subsidiary, Gerber. At all relevant times, Nestle has conducted business and derived substantial revenue through its subsidiary company, by manufacturing, advertising, distributing, selling, and marketing Baby Foods within this judicial district.

8. Defendant Plum, PBC ("Plum") is a citizen of Delaware and California with its

principal place of business located at 6795 N. Palm Ave., 2nd Floor, Fresno, CA 93704. Plum sells Baby Foods under the brand name Plum Organics. Plum's products are divided into groups according to the targeted infant or toddler age and/or type of food product. For example, there are five groups designated for the youngest infants: Stage 1 (4+ months old), Stage 2 (6+ months old), Stage 3 (6+ months old), "Super Puffs", and "Little Teethers". At all relevant times, Plum has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Baby Foods within this judicial district.

9. Defendant Campbell Soup Company ("Campbell") is a Citizen of New Jersey with its principal place of business located at One Campbell Place Camden, NJ 08103. Campbell sells food and beverages and was the parent company of Plum until the Spring of 2021. Campbell – as the parent company of Plum – sold Baby Foods under the brand name Plum Organics. Plum and Campbell's products are divided into groups according to the targeted infant and toddler age and/or type of food product. At all relevant times, as the Parent Company of Plum, Campbell conducted business and derived substantial reviews from its manufacturing, advertising, distributing, selling, and marketing of Baby Foods within this judicial district.

10. Defendant Sprout Foods, Inc. ("Sprout") is a citizen of Delaware and New Jersey with its principal place of business located at 50 Chestnut Ridge Rd, Montvale, NJ 07645. Sprout sells Baby Foods under the brand name Sprout Organic Foods. Sprout organizes its Baby Foods selection according to three categories: Stage 2 (6 months+); Stage 3 (8 months+); and Toddler. At all relevant times, Sprout has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Baby Foods within the State of California and Los Angeles County.

### **JURISDICTION AND VENUE**

11. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332. There is complete diversity of citizenship between the parties. In addition, Plaintiff seeks damages in excess of \$75,000, exclusive of interest and costs.

12. This Court has personal jurisdiction over Defendants insofar as Defendants are authorized and licensed to conduct business in the State of New York, maintain and carry on

systematic and continuous contacts in this judicial district, regularly transact business within this judicial district, and regularly avail themselves of the benefits of this judicial district.

13. Additionally, Defendants caused tortious injury by acts and omissions in this judicial district and caused tortious injury in this district by acts and omissions outside this district while regularly doing and soliciting business, engaging in a persistent course of conduct, and deriving substantial revenue from goods used or consumed and services rendered in this judicial district.

14. Venue is proper before this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claim occurred in this judicial district.

### **FACTUAL ALLEGATIONS**

#### **I. Rising Concerns Regarding the Presence of Toxic Heavy Metals in Baby Foods**

15. In October 2019, an alliance of nonprofit organizations, scientists and donors named “Happy Babies Bright Futures” (“HBBF”), dedicated to designing and implementing “outcomes-based programs to measurably reduce babies’ exposures to toxic chemicals”<sup>3</sup>, published a report investigating the presence of Toxic Heavy Metals in baby foods.<sup>4</sup> The HBBF Report tested 168 different baby foods sold on the U.S. market and concluded that “[n]inety-five percent of baby foods tested were contaminated with one or more of four toxic heavy metals—arsenic, lead, cadmium and mercury. All but nine of 168 baby foods contained at least one metal; most contained more than one.”<sup>5</sup> Specifically, the HBBF report identified “puffs and other snacks made with rice flour”, “[t]eething biscuits and rice rusks”, “infant rice cereal”, “apple, pear, grape and other fruit juices”, and “carrots and sweet potatoes” manufactured by the Defendant Baby Food Companies as particularly high in Toxic Heavy Metals.<sup>6</sup>

16. The results of the HBBF report were consistent with that of the U.S. Food and Drug Administration (“FDA”) which had, in 2017, detected one or more of the four Toxic Heavy Metals in

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<sup>3</sup> <https://www.hbbf.org/solutions>.

<sup>4</sup> Healthy Babies Bright Futures, *What’s in My Baby’s Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies’ IQ, Including Arsenic and Lead* (Oct. 2019) (“HBBF Report”), available at: [www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport\\_FULLREPORT\\_ENGLISH\\_R5b.pdf](http://www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf)).

<sup>5</sup> *Id.* at 6.

<sup>6</sup> *Id.* at 10-11

33 of 39 types of baby food tested.<sup>7</sup> However, the HBBF reported that “[f]or 88 percent of baby foods tested by HBBF—148 of 168 baby foods—FDA has failed to set enforceable limits or issue guidance on maximum safe amounts.”<sup>8</sup> The HBBF’s findings were by no means an outlier. Eight months prior to publication of the HBBF report, a study conducted by scientists at the University of Miami and the Clean Label Project “examined lead...concentrations in a large convenience sample of US baby foods.”<sup>9</sup> The study detected lead in 37% of samples.<sup>10</sup> This was consistent with findings by researchers examining baby food products in other parts of the world.

## **II. Congressional Investigation Finds Substantial Presence of Heavy Metals in Baby Foods Sparking National Outrage**

17. On February 4, 2021, the U.S. House of Representatives’ Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, published a report detailing its findings that Toxic Heavy Metals—including lead, arsenic, and mercury—were present in “significant levels” in numerous commercial baby food products.<sup>11</sup> Four companies—Hain, Gerber, Nurture, and Beech-Nut—produced internal testing policies, test results for ingredients and finished products, and documentation about what the companies did with ingredients and/or finished products that exceeded their internal testing limits. Three companies—Plum, Walmart, and Sprout—refused to cooperate.<sup>12</sup>

18. The Subcommittee reported that the data submitted by the companies unequivocally revealed that a substantial number of Defendants’ finished products and/or ingredients used to manufacture the Baby Foods are tainted with significant levels of Toxic Heavy Metals, namely lead, arsenic, and mercury.<sup>13</sup> And, where the Defendants did set internal limits for the amount of metals they allowed in their foods, Defendants routinely flouted their own limits and sold foods that consistently tested above their limits.

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<sup>7</sup> *Id.* at 6.

<sup>8</sup> *Id.* at 6.

<sup>9</sup> Gardener, et al., *Lead and cadmium contamination in a large sample of United States infant formulas and baby foods*, 651 SCI. TOTAL ENVIRON. 1, 822-827 (2019), available at: <https://www.sciencedirect.com/science/article/abs/pii/S0048969718334442?via%3Dihub>.

<sup>10</sup> *Id.*

<sup>11</sup> *See generally* Subcommittee Rpt.

<sup>12</sup> Subcommittee Rpt. at 2.

<sup>13</sup> *Id.* at 2-3.

19. **Nestle/Gerber.** Nestle and Gerber used high-arsenic ingredients, using 67 batches of rice flour that had tested over 90 ppb inorganic arsenic. Furthermore, Nestle and Gerber have regularly sold Baby Food products testing over 100 ppb arsenic, at times reaching 116 ppb. In a follow-up report in September 2021 focused on Nestle/Gerber's infant rice cereals, Congress noted that Nestle/Gerber's rice cereal tested up to 116 ppb inorganic arsenic, and its average rice cereal product contained 87.43 ppb inorganic arsenic.<sup>14</sup> While another baby food manufacturer discussed in the Congressional report (Beech-Nut) recalled some of its products and completely discontinued sales of its rice cereal, Nestle/Gerber has never taken such actions to protect children. Moreover, upon information and belief, Nestle/Gerber permitted as much as 300 ppb of arsenic in the rice flour ingredient used to manufacture their U.S. Baby Foods, notwithstanding the fact that Nestle/Gerber often implemented stricter standards for Baby Foods sold in other countries.

20. Nestle/Gerber's Baby Foods are also contaminated with elevated levels of lead. Nestle/Gerber used ingredients that tested as high as 48 ppb lead; and used many ingredients containing over 20 ppb lead. Furthermore, upon information and belief, Nestle/Gerber has sold Baby Food products testing at and/or above 50 ppb of lead. Indeed, upon information and belief, Nestle/Gerber has historically permitted as much as 150 ppb of lead into their Baby Food products. Although Nestle/Gerber was fully aware that it was very feasible—with achievability rate of 90%—to source lower-lead ingredients, the Nestle/Gerber proceeded to use high-lead ingredients in its foods. Nestle/Gerber rarely tests for mercury in its baby foods.<sup>15</sup> This, notwithstanding the fact that mercury is known to contaminate ingredients such as rice and poses a severe risk to babies' brain development.

21. Moreover, compounding these troubling findings, upon information and belief, Nestle/Gerber has historically only tested certain ingredients of its Baby Food products and rarely tested the finished products consumed by babies. Upon information and belief, it was not until

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<sup>14</sup> Staff Report, Subcommittee on Economic and Consumer Policy Committee on Oversight and Reform U.S. House of Representatives, *New Disclosures Show Dangerous Levels of Toxic Heavy Metals in Even More Baby Foods* (September 29, 2021) ("Second Congress Report"), available at: [oversight.house.gov](https://oversight.house.gov).

<sup>15</sup> *Id.* at 2-4.



recently that Nestle/Gerber started to implement finished product testing on its infant rice cereals, but none of its other Baby Food products. And Nestle/Gerber regularly flouted their own internal metal limits. Upon information and belief, regulatory testing found that a portion of Nestle/Gerber's infant rice cereals tested above 100 ppb. Such a metal level presents a risk to the neurodevelopment of babies consuming the products. Notwithstanding, the products were never recalled, and Gerber continued to market these products to vulnerable babies.

22. **Campbell/Plum.** Campbell and Plum refused to cooperate with the Subcommittee's investigation. Instead of producing any substantive information, Campbell provided the Subcommittee with a self-serving spreadsheet declaring that every one of its products "meets criteria",<sup>16</sup> while declining to state what those criteria were. Disturbingly, Campbell admitted that, for mercury (a powerful neurotoxin), Campbell and Plum have *no criterion* whatsoever, stating: "No specific threshold established because no high-risk ingredients are used."<sup>17</sup> However, despite Campbell/Plum having no mercury threshold, it still marked every food as "meets criteria" for mercury. The Subcommittee noted that "[t]his misleading framing—of meeting criteria that do not exist—raises questions about what Campbell's other thresholds actually are, and whether they exist."<sup>18</sup> This suspicion is confirmed by HBBF's independent testing which confirms the presence of Toxic Heavy Metals in Campbell/Plum's Baby Food, which found excess levels of lead, arsenic, and mercury in Campbell/Plum's Just Sweet Potato Organic Baby Foods; Just Peaches Organic Baby Food; Just Prune Organic Baby Food; Pumpkin Banana Papaya Cardamom; Apple, Raisin & Quiona Organic Baby Food; Little Teethers Organic Multigrain Teething Wafers-Banana with Pumpkin; and Mighty Morning Bar-Blueberry Lemon-Tots. Furthermore, upon information and belief, Plaintiff submits that Campbell/Plum's pattern and practice of failing to test ingredients, willingly flouting its own internal standards, and selling products notwithstanding internal acknowledgement of their high metal content, follows that of the other Defendants discussed in this Complaint, and discovery here will further flesh out the extent of Campbell/Plum's culpable conduct.

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<sup>16</sup> Campbell, *Product Heavy Metal Test Results* (Dec. 11, 2019), available at: <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/12.pdf>.

<sup>17</sup> *Id.* at 00046.

<sup>18</sup> Subcommittee Report at 45.

23. **Sprout.** Although Sprout for the most part refused to cooperate with the Subcommittee’s investigation, the Subcommittee concluded that the “handful of documents” that the company provided “displayed a lax approach to testing for toxic heavy metals in its baby food,” including by only requiring ingredient suppliers to test for heavy metals once per year.<sup>19</sup> The Subcommittee called this testing the “the most reckless among baby food sellers on the market.” In addition, independent data confirms that the Baby Food of this company is tainted with high levels of heavy metals. For example, the HBBF Report observed that Sprout’s Organic Quiona Puffs Baby Cereal Snack-Apple Kale contained 107 ppb of arsenic and 39.3 ppb lead.

24. The metal concentrations discussed above greatly surpass the limits allowed by U.S. regulatory agencies. There are no FDA regulations governing the presence of Toxic Heavy Metals in the majority of Baby Foods with the exception of 100 ppb inorganic arsenic in infant rice cereal and proposed (not yet final) limits for lead in certain baby food categories. To the extent such regulations exist, the quantities of Toxic Heavy Metals in Defendants’ Baby Foods far exceed any permissible FDA levels. To be sure, the FDA has set the maximum contaminant levels (“MCL”) in bottled water at 10 ppb inorganic arsenic, 5 ppb lead, and the EPA has capped the allowable level of mercury in drinking water at 2 ppb. However, these limits were created in reference to adult exposure, not infants. Compared to these thresholds, the test results of the Defendants’ Baby Foods and their ingredients are multiple folds greater than the permitted metal levels.

25. As found by the Subcommittee, the Defendants have willfully sold—and continue to sell—contaminated Baby Foods notwithstanding their full awareness of these unacceptably high levels of Toxic Heavy Metals in their products.

### **III. Dangers of Toxic Heavy Metals to Babies and Children**

26. According to the World Health Organization (“WHO”), Toxic Heavy Metals, specifically lead and arsenic pose a “major public health concern” for children.<sup>20</sup> The Occupational Safety and Health Administration (“OSHA”) has warned that these metals “may build up in

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<sup>19</sup> *Id.* at 3, 17-18.

<sup>20</sup> World Health Organization, *Children’s Health and the Environment WHO training Package for the Health Sector* (October 2011), available at: [https://www.who.int/ceh/capacity/heavy\\_metals.pdf](https://www.who.int/ceh/capacity/heavy_metals.pdf).

biological systems and become a significant health hazard.”<sup>21</sup> Indeed, the Department of Health and Human Services’ Agency for Toxic Substances and Disease Registry (“ATSDR”) ranks arsenic as number *one* among substances present in the environment that pose the most significant potential threat to human health, followed by lead (second), and mercury (third).

27. The threat presented by Toxic Heavy Metals to children’s health is widely shared by the global scientific community. For example, the FDA has set an Interim Reference Level (“IRL”) of 2.2 micrograms/day for lead exposure through baby food products.<sup>22</sup> That is the amount of lead exposure above which the agency considers associated with adverse neurological effects in babies. None of the Defendant Baby Food Manufacturers have ever conducted any tests or analyses to determine whether exposure to lead from their baby food products would result in children having blood lead amounts of 2.2 micrograms/day. The FDA, in its guidance documents for inorganic arsenic and lead in baby food products has repeatedly acknowledged the dangers of heavy metals to the neurodevelopment of infants.

Even low lead exposure can harm children’s health and development, specifically the brain and nervous system. Neurological effects of lead exposure during early childhood include learning disabilities, behavior difficulties, and lowered IQ. Lead exposures also may be associated with immunological, cardiovascular, renal, and reproductive and/or developmental effects...Because lead can accumulate in the body, even low-level chronic exposure can be hazardous over time...Even though no safe level of lead exposure has yet been identified for children’s health, the IRL serves as a useful benchmark in evaluating the potential for adverse effects of dietary lead. In particular, FDA is focused on the potential for neurodevelopmental effects from lead exposure, as review of the scientific literature indicates that *such adverse effects of lead consistently occur at a blood lead level associated with FDA’s IRL for children*. (emphasis added).<sup>23</sup>

28. As one recent study observed, “[t]he implications of heavy metals with regards to children’s health have been noted to be more severe compared to adults. The elements’ harmful consequences on children health include mental retardation, neurocognitive disorders, behavioral disorders, respiratory problems, cancer and cardiovascular diseases. Much attention should be given

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<sup>21</sup> OSHA, *Toxic Metals*, available at: <https://www.osha.gov/toxic-metals>.

<sup>22</sup> FDA (January 2023) *Action Levels for Lead in Food Intended for Babies and Young Children: Draft Guidance For Industry*, available at: <https://www.fda.gov/media/164684/download>.

<sup>23</sup> *Id.*

to heavy metals because of their high toxicity potential, widespread use, and prevalence.”<sup>24</sup> Children and, even more so, babies have higher exposure to metals compared to adults because they consume more food in relation to their body weight and absorb metals more readily than adults by 40 to 90%.<sup>25</sup> And, the mechanisms needed to metabolize and eliminate heavy metals are comparatively undeveloped in childhood, with babies having weaker detoxifying mechanisms and poorer immune systems than adults.<sup>26</sup> For example, liver pathways that in adulthood metabolize absorbed arsenic do not mature until mid-childhood; un-excreted arsenic thus continues to circulate and is deposited in other organs.<sup>27</sup> According to Linda McCauley, Dean of the Nell Hodgson Woodruff School of Nursing at Emory University, who studies environmental health effects, “[n]o level of exposure to these [heavy] metals has been shown to be safe in vulnerable infants.”<sup>28</sup> Thus, “the major windows of developmental vulnerability occur during infancy and early childhood due to continuing brain development after birth.”<sup>29</sup> In short, even small amounts of exposure to Toxic Heavy Metals can have devastating health outcomes for babies and children.

29. Notably, none of the Defendants ever conducted any kind of risk assessments or analyses to determine whether exposure to their baby food products exposed children to lead amounts known to harm neurodevelopment. On information and belief, exposure to Defendants’ Baby Food products exposed Plaintiff to heavy metal concentrations known to result in brain injury.

30. Indeed, upon and information and belief, Gerber (through research conducted by its parent company’s own private research group Nestle Research Center in Switzerland) has been aware

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<sup>24</sup> Osman, et al., *Exposure routes and health effects of heavy metals on children*, 32 BIOMETALS 563–573 (2019), available at: <https://link.springer.com/article/10.1007%2Fs10534-019-00193-5#citeas>.

<sup>25</sup> Stein, et al., *In harm’s way: toxic threats to child development*, 23 J DEV BEHAV PEDIATR.1 S13–S22 (2002).

<sup>26</sup> Gorini, et al., *The Role of Heavy Metal Pollution in Neurobehavioral Disorders: a Focus on Autism* 1 REV. J. AUTISM DEV. DISORD. 1, 354–372 (2014), available at: <https://link.springer.com/article/10.1007/s40489-014-0028-3>.

<sup>27</sup> Del Rio, et al., *A comparison of arsenic exposure in young children and home water arsenic in two rural West Texas communities* 17 BMC PUBLIC HEALTH 850 1-13 (2017), available at: <https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-017-4808-4>.

<sup>28</sup> Roni Caryn Rabin, *Some Baby Food May Contain Toxic Metals, U.S. Reports* (NY TIMES, Feb 4, 2021), available at: <https://www.nytimes.com/2021/02/04/health/baby-food-metals-arsenic.html>

<sup>29</sup> Gorini, et al. *supra*.

for over two decades that low levels of arsenic can harm children's neurodevelopment. Indeed, in its 2019 letter to Congress, Nestle bragged that it has access to a network of 4,800 experts, including scientists and toxicologists. Notwithstanding this, neither Gerber nor Nestle conducted any kind of risk assessments or analyses to determine whether exposure to their baby food products exposed children to lead amounts known to harm neurodevelopment until concerns regarding contaminated baby foods entered widespread public discourse in recent years.

**A. Exposure to Toxic Heavy Metals Has Been Consistently Associated with Brain Injury, i.e., Autism in Pediatric Populations**

31. It is well-known that exposure to heavy metals in early life can cause brain injury at low levels of exposure. And one of the ways in which such brain injury can present in a child is in the form of the neurodevelopmental disorders ASD. As the U.S. Centers for Disease Control observed in its 2020 Toxicological Profile for Lead, at just  $\leq 10$   $\mu\text{g/dL}$ : “The following neurobehavioral effects in children have been associated with [lead]: “Altered mood and behaviors that may contribute to learning deficits, including *attention deficits, hyperactivity, autistic behaviors, conduct disorders, and delinquency.*”<sup>30</sup> (emphasis added). Likewise, the NIH states: “prenatal and early childhood exposure to heavy metals...may be linked to autism spectrum disorder.”<sup>31</sup>

32. Multiple studies, reviews, and meta-analyses conducted throughout various parts of the world over the last decade have consistently observed that early life exposure to heavy metals can cause brain injury and, specifically, brain injury which manifests as ASD.

33. For example, four meta-analyses published in 2014, 2017, 2019 and 2020, respectively, all observed a consistent association between exposure to arsenic and mercury and ASD in children; with the authors in all three studies recommending – based on the data – that exposure to such metals in children be reduced as much as possible, and one of the study authors specifically concluding that “Results of the current meta-analysis revealed that mercury is an important causal factor in the etiology of ASD.”<sup>32</sup>

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<sup>30</sup> ATSDR (2020) *Toxicological Profile for Lead*, available at: <https://www.atsdr.cdc.gov/toxprofiles/tp13.pdf>.

<sup>31</sup> NIH, ASD & the Environment.

<sup>32</sup> Jafari, et al., *The association between mercury levels and autism spectrum disorders: A systematic review and meta-analysis* 44 J. TRACE. ELEMEN. IN MED. & BIOL. 289-297 (2017); Wang, et al.,

34. In a recent 2017 NIH-funded prospective observational study, the authors examined the risk of ASD outcome in twins based on their respective body burden of lead. The study concluded in no uncertain terms that “prenatal and early childhood disruption (excess or deficiency) of multiple metals during critical developmental windows is associated with ASD, and suggests a role for elemental dysregulation in the etiology of ASD.”<sup>33</sup>

35. Similarly, a large, prospective study from 2016 in Korean school children observed that low levels of lead exposure in early life are associated with autism, the authors specifically concluding: “even low blood lead concentrations...are associated with more autistic behaviors..., underscoring the need for continued efforts to reduce lead exposure.”<sup>34</sup>

36. Furthermore, repeated associations between early life metal exposure and ASD have also been observed during the pre-natal timeframe, lending further strength to the findings of post-natal studies. For example, in a 2021 study by Skogheim and colleagues, the authors prospectively assessed the relationship between pre-natal metal exposure in various biomarkers and autism risk. The study concluded that “[r]esults from the present study show several associations between levels of metals and elements during gestation and ASD and ADHD in children. The most notable ones involved arsenic...mercury...and lead. Our results suggest that even population levels of these compounds may have negative impacts on neurodevelopment.”<sup>35</sup> Similarly, in a study by the research group assessing the New Hampshire Birth Cohort, the authors evaluated the neurotoxic

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*Exposure to Inorganic Arsenic and Lead and Autism Spectrum Disorder in Children: A Systematic Review and Meta-Analysis*, 21 CHEM RES. TOXICOL. 32, 1904-1919 (2019), available at: <https://pubmed.ncbi.nlm.nih.gov/31549506/>; Sulaiman, et al., *Exposure to Aluminum, Cadmium, and Mercury and Autism Spectrum Disorder in Children: A Systematic Review and Meta-Analysis*, 33 Chem. Res. Toxicol. 11, 2699-2718 (2020), available at: <https://pubmed.ncbi.nlm.nih.gov/32990432/>; Yoshimasu, et al., *A meta-analysis of the evidence on the impact of prenatal and early infancy exposures to mercury on autism and attention deficit/hyperactivity disorder in the childhood*, 44 NEURO TOXICOL. 121-131 (2014), available at: <https://pubmed.ncbi.nlm.nih.gov/24952233/>.

<sup>33</sup> Arora, et al., *Fetal and postnatal metal dysregulation in autism* NATURE COMM. 1-10 (2017), available at: <https://www.nature.com/articles/ncomms15493>.

<sup>34</sup> Kim, et al., *Low-Level lead Exposure and Autistic Behaviors in School-Age Children*, 53 NEUROTOXICOLOGY 193-200 (2016).

<sup>35</sup> Skogheim, et al. *Metal and essential element concentrations during pregnancy and associations with autism spectrum disorder and attention-deficit/ hyperactivity disorder in children* 152 1-14 (2021).

effects of heavy metals during various stages of pregnancy and concluded: “Our results support the hypothesis that exposure to...As in mid to late pregnancy may be neurodevelopmentally harmful.”<sup>36</sup>

37. Moreover, such results have been replicated in studies throughout the world, including China, Korea, the U.S., Europe, and Egypt, implicating arsenic, mercury, and lead in pediatric diagnoses of autism and autistic behaviors, with a 2018 Chinese study concluding: “[t]he results of this study are consistent with numerous previous studies, supporting an important role for heavy metal exposure, particularly mercury, in the etiology of ASD.”<sup>37</sup> Indeed, a 2015 Egyptian study noted “[e]nvironmental exposure to these toxic heavy metals, *at key times in development*, may play a causal role in autism.” (emphasis added).<sup>38</sup>

38. The fact that such results, and many more, have been observed in multiple studies, conducted by different researchers, at different times, in different parts of the world, in children of multiple ages, utilizing different study methods (prospective, case-control and cross-sectional epidemiological analyses) and measuring a variety of end-points (including hair, blood, and urine), strongly supports a causal relationship between exposure to Toxic Heavy Metals and the development of ASD in children.

#### **IV. Defendants Knowingly Sold Baby Foods Containing Dangerous Levels of Toxic Heavy Metals and Knew or Should Have Known of the Risks of Such Exposures in Children**

39. During the time that Defendants manufactured and sold Baby Foods in the United

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<sup>36</sup> Doherty, et al., *Periconceptional and prenatal exposure to metal mixtures in relation to behavioral development at 3 years of age* 4 ENVIRON. EPIDEMIOL. (2020).

<sup>37</sup> Li, et al., *Blood Mercury, Arsenic, Cadmium, and Lead in Children with Autism Spectrum Disorder*, 181 BIOL TRACE ELEM RES 31-37 (2018), available at: <https://pubmed.ncbi.nlm.nih.gov/28480499/>; Ryu, et al., *Associations of prenatal and early childhood mercury exposure with autistic behaviors at 5 years of age: The Mothers and Children's Environmental Health (MOCEH) study*, 15 SCI. TOTAL ENVIRON. 251-257 (2017), available at: <https://www.sciencedirect.com/science/article/abs/pii/S0048969717316479>; Dickerson, et al., *Autism spectrum disorder prevalence and associations with air concentrations of lead, mercury, and arsenic*, 188 ENVIRON MONIT. ASSESS. 407 (2016); Mohamed, et al., *Assessment of Hair Aluminum, Lead, and Mercury in a Sample of Autistic Egyptian Children: Environmental Risk Factors of Heavy Metals in Autism* BEHAV. NEUROL. (2015), available at: <https://pubmed.ncbi.nlm.nih.gov/26508811/>; Adams, et al., *Toxicological Status of Children with Autism vs. Neurotypical Children and the Association with Autism Severity*, 151 BIOL. TRACE ELEM. RES 171-180 (2013), available at: <https://pubmed.ncbi.nlm.nih.gov/23192845/>.

<sup>38</sup> Mohamed, et al.



States, the weight of evidence showed that Defendants' Baby Foods exposed babies and children to unsafe levels of Toxic Heavy Metals. Defendants failed to disclose this risk to consumers through any means.

40. As discussed above, both independent testing, the Defendants' internal evaluations of their Baby Foods, and the Defendants' representations and disclosures to the Subcommittee and FDA reveal the presence of substantial amounts of Toxic Heavy Metals in Defendants' products. As such, Defendants knew or should have known that their Baby Foods contain dangerous of Toxic Heavy Metals.

41. Indeed, independent testing performed in early 2019 demonstrated elevated amounts of such Toxic Heavy Metals in Baby Food products on the U.S. market,<sup>39</sup> and the HBBF Report further confirmed such contamination of Defendants' Baby Foods.<sup>40</sup> And, as the Subcommittee found, the Defendants continued to sell their Baby Foods even after testing of both ingredients and finished products revealed the presence of substantial amounts of Toxic Heavy Metals.<sup>41</sup>

42. Moreover, the scientific literature on the dangers of Toxic Heavy Metals—particularly as it relates to adverse effects on the neurodevelopment of children—have been well known for decades. Defendants, as manufacturers and retailers of Baby Foods, are held to the standard of experts responsible for keeping abreast of the latest scientific developments related to the dangers of contaminants in their products. Furthermore, as alleged in more detail below, the Retailer Defendant is strictly liable for selling the Baby Foods which caused Plaintiff's harm. Defendants failed to take action in protecting vulnerable children from exposure to the Toxic Heavy Metals in their foods and, thus, subjected them to the risk of brain injury which can manifest as neurodevelopmental disorders such as ASD and related *sequalae*.

43. To be clear, the Defendants are able to manufacture Baby Foods that do not pose such a dangerous risk to the health of infants and children by using alternative ingredients, not adding certain pre-mix minerals and vitamins high in Toxic Heavy Metals, or sampling their ingredients from other sources. At the very least, Defendants were under a duty to warn unsuspecting parents of

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<sup>39</sup> See Gardener, et al., *supra*.

<sup>40</sup> See HBBF Report, *supra*.

<sup>41</sup> See, e.g., Subcommittee Report at 13-14.



the presence of Toxic Heavy Metals in their Baby Foods. However, Defendants took no action, continued to sell their products with full knowledge of the risks posed by their Baby Foods, and misled consumers regarding the safety of their products, all to the harm of children.

**V. Exemplary / Punitive Damages Allegations**

44. Defendants' conduct as alleged herein was done with reckless disregard for human life, oppression, and malice. Defendants' conduct is particularly reprehensible given that their toxic foods were directed at vulnerable babies—a population group far more susceptible than adults to the neurotoxic dangers of heavy metals.

45. Defendants were fully aware of the safety risks of Baby Foods, particularly the dangerous potential of their Baby Foods given the high content of Toxic Heavy Metals that have all been associated with brain injury in children. Nonetheless, Defendants deliberately crafted their label, marketing, and promotion to mislead consumers. Indeed, Defendants repeatedly market their Baby Foods as safe for consumption and go so far as claiming that they adhere to “the strictest standards in the world”; and provide “baby’s food full of nutrition while meeting standards strict enough for tiny tummies” as well as other statements and representations that hold out their Baby Foods as safe for consumption by infants. In actual fact, as discussed above, Defendants routinely sold Baby Foods containing astronomical amounts of Toxic Heavy Metals, regularly flouted their own internal limits of Toxic Heavy Metals in Baby Foods and failed to disclose to consumers that their products contained such dangerous contaminants.

46. This was not done by accident or through some justifiable negligence. Rather, Defendants knew they could profit by convincing consumers that their Baby Foods were harmless to humans, and that full disclosure of the true risks of the Toxic Heavy Metals present in the Baby Foods would limit the amount of money Defendants would make selling the products. Defendants' object was accomplished not only through a misleading label, but through a comprehensive scheme of selective misleading research and testing, failure to test, false advertising, and deceptive omissions as more fully alleged throughout this pleading. Parents were denied the right to make an informed decision about whether to purchase and Defendants' Baby Food for their children, knowing the full risks attendant to that use. Such conduct was done with conscious disregard of Plaintiff's rights.

47. Accordingly, Plaintiff requests punitive damages against the Defendants for the harms caused to Plaintiff.

**PLAINTIFF-SPECIFIC ALLEGATIONS**

48. Plaintiff was diagnosed with ASD at approximately 2 years of age.

49. Plaintiff started consuming Baby Food products manufactured and/or sold by the Defendants in approximately 2020 and consumed Defendants' Baby Food products at various times through early childhood.

50. Upon information and belief, the Baby Food products manufactured/marketed by Defendants and consumed by Plaintiff were all contaminated with substantial quantities of Toxic Heavy Metals, namely lead, arsenic, and mercury – exceeding that of any regulatory limits.

51. Upon information and belief, as a direct and proximate result of consuming Defendants' Baby Foods, Plaintiff was exposed to substantial quantities of Toxic Heavy Metals, namely lead, arsenic, and mercury.

52. As a direct and proximate result of consuming Defendants' Baby Foods and the exposure to the Toxic Heavy Metals therein – Plaintiff suffered brain injury which manifested as ASD and related *sequelae*.

53. Based on prevailing scientific evidence, exposure to the Toxic Heavy Metals at the levels contained in Defendants' Baby Foods can cause brain injury which can manifest as the neurodevelopmental disorders ASD and related *sequelae* in humans.

54. Had any Defendant warned Plaintiff's carers that Defendants' Baby Foods could lead to exposure to Toxic Heavy Metals or, in turn, brain injury, Plaintiff would not have consumed the Baby Foods.

55. Plaintiff alleges that as a direct and proximate result of Plaintiff's consumption of Baby Foods supplied and distributed by Defendants, Plaintiff suffered significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to brain injury which manifested as ASD and related *sequelae*.

**CAUSES OF ACTION**

**COUNT I: STRICT PRODUCTS LIABILITY – FAILURE TO WARN**

56. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

57. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, distributing, and promoting Baby Foods, which are defective and unreasonably dangerous to consumers, including Plaintiff, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Baby Foods and Toxic Heavy Metals. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Baby Foods and aimed at a consumer market.

58. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, distributed, and promoted, and otherwise released into the stream of commerce their Baby Foods, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiff, and therefore had a duty to warn of the risks associated with the consumption of Baby Foods.

59. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, and distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Baby Foods did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiff of dangers associated with Baby Foods. Defendants, as a manufacturer, seller, or distributor of food, are held to the knowledge of an expert in the field.

60. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Baby Foods because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products.

61. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of their product and to those who would foreseeably use or be harmed by Defendants' Baby Foods.

62. Even though Defendants knew or should have known that Baby Foods posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with

use and exposure to the products. The dangerous propensities of their products and the neurotoxic characteristic of Toxic Heavy Metals contained in Defendants' Baby Foods, as described above, were known to Defendants, or scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they distributed, supplied or sold the product, and were not known to end users and consumers, such as Plaintiff. The product warnings for Baby Foods in effect during the time period Plaintiff consumed Baby Foods were vague, incomplete or otherwise inadequate, both substantively and graphically, to alert consumers to the severe health risks associated with Baby Foods consumption.

63. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein, and Defendants failed to adequately warn or instruct consumers, i.e., the reasonably foreseeable users, of the risks of exposure to their products. Defendants failed to warn and have wrongfully concealed information concerning the dangerous level of Toxic Heavy Metals in their Baby Foods and the potential for consumed Baby Foods to expose children to Toxic Heavy Metals, and further, have made false and/or misleading statements concerning the safety of Baby Foods.

64. At all relevant times, Defendants' Baby Foods reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiff, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

65. Plaintiff was exposed to Defendants' Baby Foods without knowledge of their dangerous characteristics.

66. At all relevant times, Plaintiff was exposed to Defendants' Baby Foods while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

67. Plaintiff could not have reasonably discovered the defects and risks associated with Baby Foods prior to or at the time of Plaintiff consuming Baby Foods. Plaintiff relied upon the skill, superior knowledge, and judgment of Defendants to know about and disclose serious health risks associated with using Defendants' products.

68. Defendants knew or should have known that the information disseminated with their Baby Foods were inadequate, failed to communicate adequate information on the dangers of consumption, and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended and reasonably foreseeable uses.

69. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff to avoid consuming the products. Instead, Defendants disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to Baby Foods; continued to aggressively promote the safety of their products, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of consuming Baby Foods.

70. This alleged failure to warn is not limited to the information contained on Baby Foods labeling. The Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Baby Foods through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But the Defendants did not disclose these known risks through any medium. The ability to provide such warnings is not prohibited by any federal law.

71. Furthermore, Defendants possess a First Amendment Right to make truthful statements about the products they sell, and no law could lawfully restrict that constitutional right.

72. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Baby Foods, Plaintiff could have avoided the risk of developing injuries and could have obtained or used alternative products. However, as a result of Defendants' concealment of the dangers posed by their Baby Foods, Plaintiff could not have averted his injuries.

73. Defendants' conduct, as described above, was reckless. Defendants risked the lives of babies and children, including Plaintiff, with knowledge of the safety problems associated with Baby

Foods, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

74. The Defendants' lack of adequate warnings and instructions accompanying their Baby Foods were a substantial factor in causing Plaintiff's injuries.

75. As a direct and proximate result of the Defendants' failure to provide an adequate warning of the risks of Baby Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

76. **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

#### **COUNT II: STRICT PRODUCTS LIABILITY – DESIGN DEFECT**

77. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

78. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, and distributed the Baby Foods consumed by Plaintiff. These actions were under the ultimate control and supervision of Defendants.

79. At all relevant times, Defendants' Baby Food products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to infants and babies, including Plaintiff.

80. Defendants' Baby Food products as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that, when they were placed into the stream of commerce, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate.

81. Defendants' Baby Food products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in

design and formulation in that, when they left the hands of Defendants', the foreseeable risks exceeded the alleged benefits associated with their design and formulation.

82. At all relevant times, the Baby Food products consumed by Plaintiff was expected to and did reach Plaintiff without a substantial change in its condition as manufactured, handled, distributed, and sold by Defendants.

83. At all relevant times, Defendants knew or had reason to know that their Baby Food products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

84. Therefore, at all relevant times, Defendants' Baby Food products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold and marketed by Defendants were defective in design and formulation, in one or more of the following ways:

When placed in the stream of commerce, Defendants' Baby Food products were unreasonably dangerous in that they were hazardous and posed a grave risk of causing brain injury that manifests as the neurodevelopmental disorders ASD and related *sequelae* when used in a reasonably anticipated manner due to the substantial quantities of Toxic Heavy Metals in the Baby Foods; When placed in the stream of commerce, Defendants' Baby Food products contained unreasonably dangerous design defects and were not reasonably safe when used in a reasonably anticipated or intended manner; Defendants did not sufficiently test, investigate, or study their Baby Food products; Exposure to the Toxic Heavy Metals in Defendants' Baby Food products present a risk of harmful effects that outweigh any potential utility stemming from their use; Defendants knew or should have known at the time of marketing Baby Food products that exposure to their Baby Food products could result in brain injury that manifests as ASD and related *sequelae* in children; Defendants did not conduct adequate post-marketing surveillance of their Baby Food products; and Defendants could have employed safer alternative designs and formulations.

85. Plaintiff consumed Defendants' Baby Food products in an intended or reasonably foreseeable manner without knowledge of their dangerous characteristics.

86. Defendants' Baby Food products were and are more dangerous than alternative

products, and Defendants could have designed their Baby Food products to avoid harm to children. Indeed, at the time Defendants designed the Baby Food products, the state of the industry's scientific knowledge was such that a less risky design or formulation was attainable.

87. At the time the Baby Food products left Defendants' control, there was a practical, technically feasible and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Baby Foods.

88. Defendants have intentionally and recklessly defectively designed the Baby Foods with wanton and willful disregard for the rights and health of the Plaintiff, and with malice, placing their economic interests above the health and safety of the Plaintiff.

89. The design defects in Defendants' Baby Foods were substantial factors in causing Plaintiff's injuries.

90. As a direct and proximate result of the Defendants' defective design of the Baby Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to medical expenses, lost income, and other damages.

**WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

### **COUNT III: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT**

91. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

92. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, and distributed the Baby Foods consumed by Plaintiff.

93. At all relevant times, the Baby Foods consumed by Plaintiff was expected to and did reach Plaintiff without a substantial change in its condition as manufactured, handled, distributed, and sold by Defendants.

94. At all relevant times, the Baby Foods consumed by Plaintiff was used in a manner that



was foreseeable and intended by Defendants.

95. The Baby Foods consumed by Plaintiff was not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design and manufacturing specifications and/or such design and manufacture posed an unreasonable risk of harm to Plaintiff.

96. The Defendants' Baby Foods are inherently dangerous and defective, unfit and unsafe for its intended and reasonably foreseeable uses, and do not meet or perform to the expectations of parents or children.

97. The Baby Foods create risks to the health and safety of babies that are far more significant and devastating than the risks posed by other baby food products, and which far outweigh the utility of the Baby Foods products because of Defendants' manufacturing defects, which included but were not limited to: Failure to adequately inspect/test the Baby Foods during the manufacturing process; Failure to implement procedures that would reduce or eliminate the levels of Toxic Heavy Metals in Baby Foods; Failure to avoid using ingredients free from, or which contain far less, Toxic Heavy Metals to manufacture Baby Foods.

98. Defendants have intentionally and recklessly manufactured the Baby Foods with wanton and willful disregard for the rights and health of the Plaintiff, and with malice, placing their economic interests above the health and safety of the Plaintiff.

99. The manufacturing defects in Defendants' Baby Foods were substantial factors in causing Plaintiff's injuries.

100. As a direct and proximate result of the Defendants' defective manufacture of the Baby Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to medical expenses, lost income, and other damages.

**WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

**COUNT IV: NEGLIGENCE – FAILURE TO WARN**

101. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

102. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and promoting Baby Foods. Defendants knew or by the exercise of reasonable care should have known that their Baby Foods are not accompanied with adequate warnings concerning the dangerous characteristics of Baby Foods and Toxic Heavy Metals. These actions were under the ultimate control and supervision of Defendants.

103. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce their Baby Foods, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiff, and therefore had a duty to warn of the risks associated with the use of Baby Foods.

104. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Baby Foods did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiff of dangers associated with Baby Foods. Defendants, as a manufacturer, seller, or distributor of food products, are held to the knowledge of an expert in the field.

105. At the time of manufacture, Defendants could have provided warnings regarding the full and complete risks of Baby Foods and Toxic Heavy Metals because they knew or should have known use of Baby Foods was dangerous, harmful and injurious when used by Plaintiff in a reasonably foreseeable manner.

106. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of their product and to those who would foreseeably use or be harmed by Defendants' Baby Foods.

107. Defendants knew or should have known that Baby Foods posed a grave risk of harm, but failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the products. The dangerous propensities of their products and the characteristics of Toxic Heavy

Metals contained in substantial amounts in their Baby Foods, as described above, were known to Defendants, or scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they distributed, supplied or sold the product, and were not known to end users and consumers, such as the Plaintiff.

108. Defendants further breached their duty by failing to use reasonable care to adequately warn or instruct consumers (*i.e.*, the reasonably foreseeable users) of the risks of exposure to their products. Defendants failed to warn and have wrongfully concealed information concerning the dangerous level of Toxic Heavy Metals in their Baby Foods and the potential for consumed Baby Foods to expose babies and toddlers to Toxic Heavy Metals, and further, have made false and/or misleading statements concerning the safety of Baby Foods.

109. At all relevant times, Plaintiff was exposed to excessive levels of Toxic Heavy Metals through consumption of Toxic Heavy Metals while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

110. Defendants knew or should have known that the minimal warnings disseminated with their Baby Foods were inadequate, failed to communicate adequate information on the dangers and safe use/exposure, and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended and reasonably foreseeable uses.

111. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff to avoid using the product. Instead, Defendants disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to Baby Foods; continued to aggressively promote the efficacy of their products, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of consuming Baby Foods.

112. A reasonable company under the same or similar circumstance would have warned and instructed of the dangers of Baby Foods and Toxic Heavy Metals contained therein.

113. This alleged failure to warn is not limited to the information contained on the labeling of Defendants' Baby Foods. Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Baby Foods and Toxic Heavy Metals through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But the Defendants did not disclose these known risks through any medium.

114. Furthermore, Defendants possess a First Amendment Right to make truthful statements about the products they sell, and no law could lawfully restrict that constitutional right.

115. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Baby Foods, Plaintiff could have avoided the risk of developing injuries and could have obtained or used alternative products. However, as a result of Defendants' concealment of the dangers posed by their Baby Foods, Plaintiff could not have averted his injuries.

116. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety problems associated with Baby Foods, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

117. The Defendants' lack of adequate warnings and instructions accompanying their Baby Foods were a substantial factor in causing Plaintiff's injuries.

118. As a direct and proximate result of the Defendants' failure to provide an adequate warning of the risks of Baby Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

119. **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

**COUNT V: NEGLIGENT PRODUCT DESIGN**

120. The Defendants knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of Baby Foods.

121. The Defendants owed a duty to all reasonably foreseeable users to design a safe product.

122. The Defendants breached their duty by failing to use reasonable care in the design of Baby Foods because the product exposed users to unsafe levels of Toxic Heavy Metals.

123. The Defendants breached their duty by failing to use reasonable care in the design of Baby Foods by negligently designing the Baby Foods with ingredients and/or components high in Toxic Heavy Metals.

124. The Defendants breached their duty by failing to use reasonable care in the design of Baby Foods by negligently designing and formulation, in one or more of the following ways:

When placed in the stream of commerce, Defendants' Baby Foods were defective in design and formulation, and, consequently, dangerous to an extent beyond that which an ordinary consumer would contemplate;

When placed in the stream of commerce, Defendants' Baby Foods were unreasonably dangerous in that they were hazardous and posed a grave risk of neurodevelopmental disorders and other serious illnesses when used in a reasonably anticipated manner;

When placed in the stream of commerce, Defendants' Baby Foods contained unreasonably dangerous design defects and were not reasonably safe when used in a reasonably anticipated or intended manner;

Defendants did not sufficiently test, investigate, or study their Baby Foods and, specifically, the content of Toxic Heavy Metals in the ingredients used to manufacture the foods and/or the finished products;

Defendants did not sufficiently test, investigate, or study their Baby Foods and, specifically, the ability for Baby Foods to expose babies to high amounts of Toxic Heavy Metals;

Exposure to Baby Foods presents a risk of harmful effects that outweigh any potential utility stemming from the use of the products;

Defendants knew or should have known at the time of marketing Baby Foods that exposure to Toxic Heavy Metals contained in the Baby Foods could result in brain injury that manifests as ASD and other severe illnesses and injuries;

- a. Defendants did not conduct adequate post-marketing surveillance of their Baby Foods; and
- b. Defendants could have employed safer alternative designs and formulations. For example, the Defendants could have avoided use of certain ingredients high in Toxic Heavy Metals, avoided using pre-mix vitamins high in Toxic Heavy Metals, and/or sampled their ingredients from other sources.

125. The Defendants breached their duty by failing to use reasonable care by failing to use cost effective, reasonably feasible alternative designs. There was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Baby Foods.

126. A reasonable company under the same or similar circumstances would have designed a safer product.

127. Plaintiff was harmed directly and proximately by the Defendants' failure to use reasonable care in the design of their Baby Foods. Such harm includes significant exposure to Toxic Heavy Metals, which can cause or contribute to brain injury that manifests as ASD and related *sequelae*.

128. Defendants' defective design of Baby Foods was willful, wanton, malicious, and conducted with reckless disregard for the health and safety of consumers of the Baby Foods, including Plaintiff.

129. The defects in Defendants' Baby Foods were substantial factors in causing Plaintiff's injuries.

130. As a direct and proximate result of the Defendants' defective design of the Baby Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

131. **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

**COUNT VI: NEGLIGENT MANUFACTURING**

132. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

133. At all relevant times, the Defendants manufactured, tested, marketed, sold, and distributed the Baby Foods that Plaintiff consumed.

134. The Defendants had a duty to exercise reasonable care, in the manufacturing, testing, marketing, sale, and distribution of Baby Foods.

135. The Defendants knew or, by the exercise of reasonable care, should have known, use of Baby Foods were carelessly manufactured, dangerous, harmful and injurious when used by Plaintiff in a reasonably foreseeable manner.

136. The Defendants knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of Baby Foods improperly manufactured, tested, marketed, distributed, and sold.

137. Without limitation, examples of the manner in which Defendants breached their duty to exercise reasonable care in manufacturing Baby Foods, included:

- a. Failure to adequately inspect/test the Baby Foods during the manufacturing process;
- b. Failure to implement procedures that would reduce or eliminate levels of Toxic Heavy Metals in Baby Foods; and
- c. Failure to avoid using ingredients free from, or which contain far less, Toxic Heavy Metals to manufacture Baby Foods.

138. A reasonable manufacturer under the same or similar circumstances would have implemented appropriate manufacturing procedures to better ensure the quality and safety of their product.

139. Plaintiff was harmed directly and proximately by the Defendants' failure to use

reasonable care in the manufacture of their Baby Foods. Such harm includes significant exposure to a Toxic Heavy Metals, which can cause or contribute to brain injury which manifests as ASD and related *sequalae*.

140. Defendants' improper manufacturing of Baby Foods was willful, wanton, malicious, and conducted with reckless disregard for the health and safety of users of the Baby Foods, including Plaintiff.

141. The defects in Defendants' Baby Foods were substantial factors in causing Plaintiff's injuries.

142. As a direct and proximate result of the Defendants' improper manufacturing of Baby Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

143. **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

**JURY TRIAL DEMAND**

144. Plaintiff demands a trial by jury on all the triable issues within this pleading.

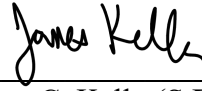
**PRAYER FOR RELIEF**

145. WHEREFORE, Plaintiff requests the Court to enter judgment in Plaintiff's favor and against the Defendants for:

- a. actual or compensatory damages in such amount to be determined at trial and as provided by applicable law;
- b. exemplary and punitive damages sufficient to punish and deter the Defendants and others from future wrongful practices;
- c. pre-judgment and post-judgment interest;
- d. costs including reasonable attorneys' fees, court costs, and other litigation expenses;
- and
- e. any other relief the Court may deem just and proper.



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